

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No. 10/670,004
Attorney Docket No. Q77153

REMARKS

Claim 1 has been amended to incorporate the subject matter of claims 2 and 3, and to recite a preferred molar ratio of phosphatidylserine ("PS") to phosphatidylcholine ("PC"). Upon entry of the Amendment, claims 1 and 4-6 will be pending in the application. Claims 2 and 3 have been canceled. Support for the amendment to claim 1 reciting the molar ratio of PS to PC can be found in the specification, such as in Example 2. Therefore, no new matter has been added.

I. Response to claim rejections - 35 U.S.C. § 112

Claims 1-6 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Claim 1 presently recites that the active ingredient comprises a benzimidazole derivative having suppressing action on foaming of macrophages.

Referring to page 2 of the Office Action, the Examiner asserts that the specification does not reasonably provide enablement for an active ingredient or benzimidazole derivative.

At page 4, lines 8-13, the specification describes as follows:

Benzimidazole derivatives that strongly suppress foaming of macrophages and have reduced side effects are known, and they can be most preferably used for manufacture of the liposome of the present invention (Japanese Patent Unexamined Publication Nos. 6-48942 and 7-228530, International Patent Publication WO95/21160, Japanese Patent Unexamined Publication Nos. 9-31062 and 9-40669).

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In this regard, the specification describes that the claimed benzimidazole derivatives are known to persons skilled in the art. Specifically, the specification describes that the claimed benzimidazole derivatives are those disclosed in Japanese Patent Unexamined Publication Nos. 6-48942 and 7-228530, International Patent Publication WO95/21160, and Japanese Patent Unexamined Publication Nos. 9-31062 and 9-40669. As a result, a person skilled in the art can produce the claimed benzimidazole derivative by looking to any one of Japanese Patent Unexamined Publication Nos. 6-48942 and 7-228530, International Patent Publication WO95/21160, and Japanese Patent Unexamined Publication Nos. 9-31062 and 9-40669. Claim 1 does not encompass all types of benzimidazole derivatives, as it recites “a benzimidazole derivative having suppressing action on foaming of macrophages.” As such, a person skilled in the art can make and use the claimed benzimidazole derivative without undue experimentation.

Claim 2 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

The Examiner asserts that the phrase “benzimidazole derivative having suppressing action on foaming of macrophages” is unclear.

As described above, page 4 of the specification describes that the claimed benzimidazole derivatives are those disclosed in Japanese Patent Unexamined Publication Nos. 6-48942 and 7-228530, International Patent Publication WO95/21160, and Japanese Patent Unexamined Publication Nos. 9-31062 and 9-40669. As such, the specification defines “a benzimidazole derivative having suppressing action on foaming of macrophages” as those disclosed in Japanese Patent Unexamined Publication Nos. 6-48942 and 7-228530, International Patent Publication

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WO95/21160 and Japanese Patent Unexamined Publication Nos. 9-31062 and 9-40669. A person skilled in the art can understand the metes and bounds of the phrase, based on the description in the present specification.

II. Response to claim rejections - 35 U.S.C. § 102

(A) Claims 1 and 3-6 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,660,855 to Male-Brune (“the ‘855 Patent”).

Claim 1 presently recites that the active ingredient comprises a benzimidazole derivative having suppressing action on foaming of macrophages.

In contrast, the Abstract of the ‘855 Patent discloses producing a liposome formulation of 6-(cholest-5-en-3 β -yloxy)hexyl-6-amino-6-deoxy-1-thio- α -D-mannopyranoside. In this regard, the ‘855 Patent fails to describe, teach or suggest the liposome presently recited in claim 1.

(B) Claims 1-6 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by GB 2 184 013 (“GB ‘013”).

The Abstract of GB ‘013 discloses producing a liposome including 5-benzoyl-2-benzamidazole carbamate for the treatment of hydatidosis and alveococcosis. Further, GB ‘013 discloses that 5-benzoyl-2-benzamidazole carbamate is used to treat hydatidosis and alveococcosis.

However, 5-benzoyl-2-benzamidazole carbamate is different from the claimed benzimidazole derivative having suppressing action on foaming of macrophages. In this regard, GB ‘013 fails to describe, teach or suggest the liposome presently recited in claim 1.

(C) Claims 1-6 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 0 583 665 (“EP ‘665”).

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Page 33 of EP '665 discloses a pharmaceutical test, in which test compounds, liposomes, and 3H-Oleic acid are added to cultures of macrophages. EP '665 also discloses benzimidazole compounds that are used to treat hyperlipidemia and arteriosclerosis. *See*, Abstract.

EP '665 fails to disclose preparing the liposomes so that the liposome contains the benzimidazole compounds thereof. The pharmaceutical test discloses that the test compounds and liposomes are added separately to the cultures of macrophages. EP '665 thus fails to describe, teach or suggest a liposome containing the benzimidazole compounds thereof. The liposome disclosed in EP '665 is used for the purpose of introducing cholesterol. EP '665 fails to describe, teach or suggest the liposome presently recited in claim 1.

In addition, claims 4-6 depend directly or indirectly from claim 1. Therefore, claims 4-6 are novel and unobvious for at least the same reasons as claim 1.

Reconsideration and withdrawal of the above rejections under 35 U.S.C. § 102 are respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

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CUSTOMER NUMBER


Ken Sakurabayashi
Registration No. 58,490

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